IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:			
Leslie D. MICHELSON *et al.*		Art Unit:	3626
Appln. No.:	09/923,385	Examiner:	Alexander Kalinowski
Filed:	August 8, 2001	Confirmation No.:	2406
For:	Systems and Methods for Selecting and Recruiting Investigators and Subjects for Clinical Studies	Atty. Docket:	16602.003

Request for Reinstatement of Appeal

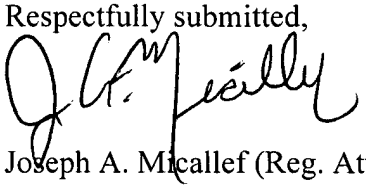
Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. § 1.193(b)(2), Applicants hereby request that the appeal of the above-referenced application be reinstated. A Supplemental Appellant's Brief is submitted herewith.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any additional fees are required in the present application, including any fees for extensions of time, authorization to charge such fees is given in the accompanying transmittal letter.

Respectfully submitted,



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Date: June 14, 2004

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Application of:

MICHELSON *et al.*

Appln. No.:	09/923,385	Art Unit:	3626
Filed:	August 8, 2001	Examiner:	A. G. Kalinowski
For:	SYSTEMS AND METHODS FOR SELECTING AND RECRUITING INVESTIGATORS AND SUBJECTS FOR CLINICAL STUDIES	Atty. Docket:	16602.003
		Confirmation No.:	2406

SUPPLEMENTAL APPELLANT'S BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is a Supplemental Appeal under 37 C.F.R. § 1.191 from the decision of the Examiner as set forth in the final Official Action dated February 27, 2004. In that Action, claims 2-15 and 129-151 were finally rejected. *This Brief is submitted in triplicate.*

Applicants filed an Appellants' Brief on July 31, 2003. After receiving an Official Action mailed October 7, 2003, stating that the Appellants' Brief was defective, Applicants filed an Amended Appellants' Brief on November 5, 2003. On February 27, 2004, Applicants received an Official Action withdrawing the prior rejections and setting forth new grounds of rejection.

A Request for Reinstatement of the Appeal is filed herewith.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Applicants do not believe any additional fees are due in conjunction with this filing. However, if any fees are required in the present application, including any fees for extensions of time, authorization to charge such fees is given in the accompanying transmittal letter.

1. Real Party in Interest

The real party in interest is Acurian, Inc., a Delaware corporation with offices at 2 Walnut Grove Drive, Suite 375, Horsham, PA 19044.

2. Related Appeals and Interferences

Appellant is unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 2-15 and 129-151 are pending. Claims 1 and 16-128 have been cancelled without prejudice. Claims 2, 129, 138, 139, 140, 149, 150, and 151 are independent. Claims 14 and 15 stand rejected under 35 U.S.C. § 112 second paragraph. Claims 2-14 and 129-151 stand rejected under 35 U.S.C. § 103(a). Applicants appeals all of the rejections of each of the claims.

4. Status of Amendments

The Amendment filed March 4, 2003, was entered by the Examiner in the Official Action mailed June 3, 2003.

5. Summary of Invention

The invention is directed to a novel, integrated on-line interactive forum that promotes the exchange of information among clinical study sponsors, clinical study investigators, and potential participants in the clinical study. The system includes novel systems and methods for exchanging information among sponsors, investigators, and potential study subjects and for recruiting, selecting and enrolling appropriate subjects for clinical studies. Prior art systems provided information regarding clinical studies to potential participants, but left those participants to their own devices to seek participation in or enroll in the studies. Other prior systems provided automated enrollment in specific studies once a patient had been informed of the study and been judged by an investigator (i.e., a physician) to be appropriate. The present invention, however, can provide a single, Web-based interface that supplies information about various clinical trials, accepts enrollment information for those trials, automatically determines if the prospective patient is appropriate for the trials, automatically notifies the patient if they are

an appropriate participant for a study and automatically gathers additional information from those patients so notified. Through this novel, integrated and automated approach, significant efficiencies are realized by bringing together sponsors, investigators and study subjects in one forum and by automatically evaluating and notifying prospective subjects.

6. Issues

The issues in this Appeal are:

(a) whether claims 2-15 and 129-151 are unpatentable under 35 U.S.C. § 103(a) as being obvious over a combination of references including a published U.S. patent application to Knight, U.S. Pub. No. 2002/0099570 (hereinafter Knight);

(b) whether claims 2, 4-14 and 130-151 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Baldwin, Gary (hereinafter Baldwin) in view of information available at the web site of CenterWatch (hereinafter CenterWatch) and Knight;

(c) whether claims 3 and 129 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Baldwin, CenterWatch and Knight and further in view of "TVisions Wins Top Web Extranet Award, Recognized for Creative, Life-Saving Site" (hereinafter TVisions);

(d) whether claim 15 is unpatentable under 35 U.S.C. § 103(a) as being obvious over Baldwin, CenterWatch and Knight and further in view of Larkin, Marilynn, "Physicians accelerate onto the Internet" (hereinafter Larkin);

(e) whether claim 14 is unpatentable under 35 U.S.C. § 112, second paragraph, as being indefinite because of use of the limitation "other off-line sources;" and

(f) whether claim 15 is unpatentable under 35 U.S.C. § 112, second paragraph, as being indefinite because of use of the limitation "the step of automatically determining further includes reference to the genetic sequence information associated with a person registered in the database."

7. Grouping of Claims

Claims 2-15 and 129-151 remain in this case. Claims 1, 129, 138, 139, 140, 149, 150, and 151 are independent. All of the claims at issue do not stand or fall together. Claims 2-15 and 129-151 are separately patentable from the other claims at issue. Claims 2, 4-14 and 130-151 are separately patentable from the other claims at issue. Claims 3 and 129 are separately patentable from the other claims at issue. Claim 15 is separately patentable from the other claims at issue. Claim 14 is separately patentable from the other claims at issue. An explanation as to why the claims of each group are separately patentable is provided in section 8 below.

8. The Rejections, Prior Art of Record, and Enablement

A. Each Of The Pending Claims Has Been Rejected Based On The Improper Combination Of Various References With Knight[1]

In three separate rejections encompassing all the pending claims, the Examiner has asserted that various combinations of references render the claims unpatentable pursuant to 35 U.S.C. § 103(a). *Office Action* at 4-17. In each case the Examiner relies on a published U.S. patent application to Knight in order to meet important elements of the claims. *Id.* Knight, however, is not prior art to the present application and can therefore not properly be used as a basis for rejecting Applicants' claims.

The present application was filed on August 8, 2001 and claims the benefit of a PCT filed on January 29, 2001 and a provisional application No. 60/178,634, filed January 26, 2000. The Knight application was filed on August 23, 2001 and claims the benefit of provisional application number 60/227,484, filed August 24, 2000. The relationship of the various filing dates therefore can be depicted as follows:

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[1] All of the prior art rejections asserted by the Examiner depend on Knight and those rejections encompass each of the pending claims. Thus, if the Examiner's reliance on Knight is improper, as argued here, all of the Examiner's prior art rejections must be reversed. That would leave all of the pending claims ready for allowance, except for two. Claims 14 and 15 have also been rejected under 35 U.S.C. § 112, second paragraph as indefinite. *Office Action* at pages 3-4. The indefiniteness rejections have also been appealed from and are addressed below.

Present Application	Knight Application
Provisional Filing Date of January 26, 2000	
	Knight Provisional Filing Date of August 24, 2000
PCT Filing Date of January 29, 2001	
Filing Date of Present Application of August 8, 2001	
	Knight Utility Application Filing Date of August 23, 2001

As is apparent from the above chart, Knight cannot be considered prior art to the present application if (1) the present application is entitled to its own provisional application's filing date or (2) if Knight is not entitled to its own provisional filing date.[2] As demonstrated below, both of these propositions are true. Knight is therefore not prior art and each of the rejections relying on Knight must be rejected.

(1) Applicants Are Entitled To Their Own Provisional Application's Filing Date, Which Removes Knight As A Reference

The present application includes a claim to the filing date of Provisional Application No. 60/178,634 and the Examiner has never disputed either copendency or common inventorship. Indeed, both requirements are indisputably met on the present record. The Examiner has, however, argued that the pending claims are not entitled to the benefit of the January 2000 provisional filing date because the provisional application does not enable the claim language

[2] It is undisputed that the present application is entitled to the benefit of its PCT application filing date.

"automatically presenting questionnaires" and "presenting questionnaires." *Office Action* at 2. The Examiner is incorrect in this conclusion.

The claim elements in question are directed to presenting a questionnaire to a patient (or the patient's caregiver) on a web page once the patient has completed various steps in order to register with a database over a computer network. Claim 2 is exemplary in this context:

> 2. A method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:
>
> (a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database, wherein the registration information includes at least a geographic location of the person, at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies;
>
> (b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information;
>
> (c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person;
>
> (d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice;
>
> (e) ***automatically presenting a questionnaire*** associated with the given clinical study to the person or caregiver ***after step (d)***; and
>
> (f) storing answers submitted by the person or caregiver in the database.

(Emphasis added.)

Applicants' provisional application states that "the present invention is directed to a method and system for creating secure databases ... and allowing access by appropriate parties to these databases over a network." *Provisional Application No. 60/178,634* at 4. It specifically states that the "system also includes a web site 320 through which a variety of information may be accessed." *Provisional Application No. 60/178,634* at 8. And it specifically describes the use of the system software to support account sign-up and management, demographics capture, personalization of target audiences and the matching of "participant entered data" against trial criteria:

> The system includes software that supports account sign-up, management, demographics capture, and personalization of target audiences. A core personalization and registration infrastructure supports ad-hoc user properties, profile, and behavioral data collection, content targeting, useful site and usage reporting, and specified user views. The views provide the specific information each sponsor needs, and ensures confidential and proprietary data is shielded from competitors.
>
> The software includes proprietary database matching that enables a comparison of the participant profile to the trials protocol criteria. For example, templates are established for certain protocols and performing database matching to compare this information against the participant entered data.

Provisional Application No. 60/178,634 at 9.

It is true that the above passage does not use the phrase "automatically presenting questionnaires" *verbatim*, but there can hardly be any argument that web-based software for supporting "account sign-up, management, [and] demographics capture" and which "supports ad-hoc user properties, profile, and behavioral data collection, content targeting, useful site and usage reporting, and specified user views" is referring to the use of some type of questionnaire in order to obtain the information from the user. If there were any doubt, the application's description of comparing trial criteria to "participant entered data" removes it.

Indeed, it is difficult to imaging how such a system would perform that functionality absent presenting a questionnaire to the user. Certainly, the Examiner has identified no alternative interpretation of that passage that one of ordinary skill in the art might hold.

Further, it is important to note that the Examiner's conclusion that the claims were not entitled to the earlier filing date rested on an asserted lack of *enablement* by the provisional application. That conclusion, even ignoring the clear teaching quoted above, is at odds with the earlier conclusion by the same Examiner that the prior art does embrace "automatically presenting questionnaires."

In particular, in an Official Action mailed December 4, 2002, the Examiner stated that "[U.S. Patent No. 5,991,731 to] Colon discloses (e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d) ..." and cited specific passages in Colon to support this view.[3] The Examiner then argued that the Colon patent's disclosure of entering data into a computer system through the use of "input forms" taught "automatically presenting a questionnaire:"

> A careful reading of Colon discloses that the Colon method "captures data in its database through appropriate input forms developed for the specific clinical study (see col. 1, lines 64-67)." Clearly, the Colon method provides forms for user input that is to be entered into the database. The forms provide instructions (i.e. questionnaire) for the user to input information required by the clinical study. Therefore, Colon discloses automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d)... .

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[3] The specific passages cited by the Examiner were as follows:

> "(... the study will also include followup visits and the operation of the system for these consultations with a physician at participating sites ... followup data, endpoint data and significant events data is entered and after verification is transmitted through the Internet server 13 to the database host computer 11 for input to tables 51, 52, 53.)(col. 7, lines 8-37)."

Office Action at 13.

Office Action at 5.

Indeed, the suggestion that the average artisan did not possess the skill to "automatically present[] questionnaires" at a time when the Internet and World Wide Web were well known and nearly omnipresent is belied not only by common experience, but by the other references the Examiner cited as disclosing this functionality. In an Official Action mailed June 3, 2003, for example, the Examiner argued that a publication entitled "drkoop.com & Quintiles Launch Service to Recruit Clinical Trial Patients on the Internet" also disclosed automatically presenting questionnaires. According to the Examiner, "drkoop discloses presenting a screening questionnaire associated with the clinical study" and cites "... interactive questionnaire to pre-screen potential participants ... responses are evaluated to determine if they meet the trial's basic criteria. ..." and points to page 2, lines 18-26. *See Office Action mailed June 3, 2003* at 26.

A finding of lack of enablement requires a determination that undue experimentation would be required by a person skilled in the pertinent art in order to make and use the invention. *Northern Telecom, Inc. v. Datapoint Corporation*, 908 F.2d 931, 941; 15 U.S.P.Q.2d 1321 (Fed. Cir. 1990). Given the clear description of software for performing this functionality in Applicants' provisional application and the undisputed evidence that "automatically presenting questionnaires" was within the skill of the average practitioner in this art, the Examiner's conclusion that the provisional application does not enable the pending claims is clearly wrong. The claims are entitled to the provisional application's date and Knight is, therefore, not prior art.

(2) Knight Is Not Entitled To Its Provisional Application Filing Date Because It Lacks Common Inventorship, Which Removes Knight As A Reference

The Examiner did not explain why he believed the Knight application could be considered prior art to the present application. He is apparently relying on Knight's provisional

filing date pursuant to Section 119(e)(1).[4] That section, however, requires common inventorship between the two applications:

> An application for patent filed under section 111(a) or section 363 of this title for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in a provisional application filed under section 111(b) of this title, ***by an inventor or inventors named in the provisional application,*** shall have the same effect, as to such invention, as though filed on the date of the provisional application filed under section 111(b) of this title, if the application for patent filed under section 111(a) or section 363 of this title is filed not later than 12 months after the date on which the provisional application was filed and if it contains or is amended to contain a specific reference to the provisional application.

(Emphasis added.)

Indeed, this plain statutory language has been confirmed by the court of appeals, which has held "...for the non-provisional utility application to be afforded the priority date of the provisional application, the two applications must share at least one common inventor..." *New Railhead Manufacturing, L.L.C. v. Verneer Manufacturing Company,* 298 F.3d 1290; 1294 63 U.S.P.Q.2d 1843 (Fed. Cir. 2002).

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[4] The Examiner did not cite a specific statutory basis supporting the use of the Knight application as prior art. *Office Action* at 4-17. The Knight application was published on July 25, 2002, many months after the filing date of the present application. *U.S. Patent Application Publication No. US 2002/0099570 A1.* The Knight application therefore cannot be considered a publication for purposes of Sections 102(a) or (b). Nor is there anything in the Examiner's Office Action or the record generally that would suggest the applicability of Sections 102 (c), (d), (f), or (g). Thus, the only statutory provision that could even arguably permit Knight to be considered prior art is Section 102(e)(1). Under that section, however, Knight may not be considered prior art unless it was "filed ... before the invention by the applicant for patent." 35 U.S.C. § 102(e)(1). Since Knight's filing date (August 23, 2001) is after the filing date of the present application (August 8, 2001), the only way Knight could arguably qualify as prior art under Section 102(e) is if Knight is entitled to the benefit of his provisional filing date (August 24, 2000) pursuant to 35 U.S.C. § 119.

The Knight application relied on by the Examiner (U.S. Application No. 09/938,295) names a single inventor, Stephen C. Knight. *U.S. Patent Application Publication No. US 2002/0099570 A1.* That provisional application to which it claims priority, however, does not name Knight as an inventor. It lists only Michael Barrow, Aric LeDell, Christine Joyce, Peter Fernandez, Douglas Murphy, Robert Adelman, M.D., and Joshua Schultz as co-inventors. *Provisional Application Number 60/227,484.*

The Knight application is therefore not entitled to the benefit of the provisional filing date. Its priority date is limited to its own filing date of August 23, 2001. Applicants' filing date is August 8, 2001 and they are undeniably entitled at least to the benefit of their PCT filing date of January 29, 2001. Knight is not prior art to the present invention.

Accordingly, because each prior art rejection asserted by the Examiner requires Knight to meet the elements of the claims, and Knight is not prior art on which the Examiner may rely, each prior art rejection asserted by the Examiner is improper and must be reversed.

B. Even If Knight Is Prior Art The Examiner Has Improperly Combined References

This is a reinstated appeal of the Examiner's rejections. In the original appeal, Applicants sought to overturn several different obviousness-based rejections in which the Examiner sought to combine, in various ways, five different prior art references to meet all the elements of the claims. Here, the Examiner similarly asserts five references in various combinations, though not all the same references as previously asserted. In fact, during the course of this prosecution the Examiner has seen it necessary to assert seven different references in order meet all the elements of the claims. This is powerful evidence of the non-obviousness of the claims and that, absent use of Applicants' specification as a template, one of ordinary skill in the art would not have thought to create a system as claimed here.

Indeed, while the Examiner in most cases can point to some disclosure somewhere in this new myriad of references for each element of the claim, nowhere is there a real motivation to combine those references. Instead, the Examiner cites only vague reasons why a particular

reference might be advantageous and relies on that to combine it with whatever is necessary to meet the other elements of the claim. As demonstrated below, this is hindsight reconstruction using Applicants' claims as a guide and must therefore be reversed. *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 314, 315; 227 USPQ 766 (Fed. Cir. 1985).

(1) The Rejection of Claims 2, 4-14, and 130-151 Under 35 U.S.C. § 103(a)

In the Official Action mailed February 27, 2004, claims 2, 4-14, and 130-151 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Baldwin in view of CenterWatch and Knight. The Examiner has cited two different motivations to combine the three references he deemed necessary to meet the elements of the claims.

(a) The Cited Motivation "Providing Clinical Trial Matching Information For Patient And Research Professionals Interested In Information On And/Or Participating In Clinical Trials" Does Not Support The Asserted Combination

First, the Examiner combined the CenterWatch and Baldwin references based on an alleged motivation found in the CenterWatch document of "providing clinical trial matching information for patient and research professionals interested in information on and/or participating in clinical trials." *Office Action* at 5-6, 9, and 10. He deemed this combination necessary because Baldwin did not disclose the use of "geographic location" information as claimed, for example, in the following step:

> presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database, ***wherein the registration information includes at least a geographic location of the person***

See present application, claim 2.

The cited motivation, however, has nothing to do with using geographic location information in prior art systems as claimed and he never explains why this vague motivation would lead the artisan to Baldwin, instead of to some other reference that did not include the other elements of the claims. This is therefore not motivation to combine, but a justification for creating a combination suggested only by Applicants' disclosure.

In addition, regarding the rejection of claims 10 and 13, CenterWatch does not teach anything having to do with the geographic location of the *clinical trial*, as claimed.[5] At most it discusses requesting the participant for his or her location. *See CenterWatch Patient Notification Services* at 2.

(b) The Cited Motivation "Accelerating Clinical Trial Recruitment" Does Not Support The Asserted Combination

Next, the Examiner combined the CenterWatch and Baldwin references with Knight based on an alleged motivation found in the Knight document of "accelerating clinical trial recruitment." *Office Action* at 5-7 and 11-14.[6] This combination was necessary to the

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[5] Claim 10 includes language that is different from claim 2:

> "The method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of the given clinical study."

As does claim 13:

> "The method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of an investigator associated with the study."

[6] During the discussion of the rejection of claims 2, 4-14 and 130-151 over Baldwin, CenterWatch and Knight, *see Office Action* at 4-14, the Examiner refers to a prior art reference called "TVisions." *See Office Action* at 12 and 14. No discussion of that reference appears in this section and Applicants assume its inclusion there is a mistake. To the extent it is not, Applicants assert that the Examiner has included no discussion whatsoever of why one of ordinary skill in the art would be motivated to include that reference in the cited combination.

Examiner's rejection because neither Baldwin nor CenterWatch taught the use of "questionnaires" as claimed.[7]

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[7] Claim 2 includes the following language:

> "A method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:... (e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d);... "

Claim 4 includes the following language:

> "The method of claim 2, wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study."

Claim 5 includes the following language:

> "The method of claim 2, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site."

Claim 130 includes the following language:

> "The method of claim 2, wherein said questionnaire is a pre-examination questionnaire."

Claim 131 includes the following language:

> "The method of claim 130, wherein said pre-examination questionnaire is a screening questionnaire."

Claim 132 includes the following language:

> "The method of claim 130, wherein said pre-examination questionnaire is a pre-screening questionnaire."

Claim 133 includes the following language:

> "The method of claim 2, wherein said questionnaire is a pre-screening questionnaire."

Claim 134 includes the following language:

> "The method of claim 2, wherein said questionnaire is a screening questionnaire."

Claim 135 includes the following language:

Again, however, the cited motivation has nothing to do with adding the presentation of a questionnaire, or any particular type of questionnaire, to prior art systems. It may be that the system of Knight would accelerate clinical trial recruitment, but Knight never states that this is due to the use of questionnaires. Indeed, the Examiner never explains why this vague motivation would lead the artisan from Knight to Baldwin and CenterWatch, instead of to some other references that do not meet the other claims elements.

In fact, the addition of various questionnaires would not necessarily accelerate clinical trial recruitment. Adding these additional criteria could, in some circumstances, actually slow the recruitment process since it will take longer to actually get patients enrolled in a study. Patients may have to leave the questionnaire and hunt for specific information, such as medical records, family histories, or other sources of information. This could take a considerable amount of time, drastically slowing clinical trial recruitment. Patient may never return to the questionnaire because they can't find the information, they are frustrated with the process, or they forget to return. Thus, the addition of a questionnaire would not necessarily be motivated by a desire to "accelerat[e] clinical trial recruitment," at least not with a specific statement in the prior art linking the two concepts.[8]

> "The method of claim 134, wherein said screening questionnaire is protocol specific."

Claim 136 includes the following language:

> "The method of claim 2, wherein said questionnaire is designed for screening for clinically appropriate persons."

Claim 137 includes the following language:

> "The method of claim 2, wherein said questionnaire requests information regarding inclusion/exclusion criteria."

[8] The Examiner has also summarily rejected claims 138-151 on the basis that those claims are "similar in scope" to various other rejected claims. *Office Action* at 14. In particular, the Examiner asserts that claim 138 is similar in scope to claim 131, that claims 139 and 140 are similar in scope to claim 138, that claims 141-148 are similar in scope to claims 130-137, and that claims 149-151 are similar in scope to claim 138. *Id.* No additional reasons for rejecting these claims are provided. *Id.* The rejection of these claims is therefore improper for all of the same reasons argued above.

(2) The Rejection of Claims 3 and 129 Under 35 U.S.C. § 103(a)

(a) The Cited Motivation "Alerting Physicians Within Seconds Of Possible Matches Of Their Patients With Available Or New Clinical Trials" Does Not Support The Asserted Combination

The Examiner rejected claims 3 and 129 on the combination of the Baldwin, CenterWatch and Knight references with document referred to as "TVisions". The Examiner concluded that Baldwin, CenterWatch and Knight do not teach or suggest the "accessing or amending information in the database" limitations of these claims.[9] The alleged motivation for this combination is that the TVisions document suggests "alerting physicians within seconds of possible matches of their patients with available or new clinical trials". *Office Action* at 15-16.

Once again, however, the asserted motivation has nothing to do with the missing element and suggests nothing of the particular combination relied upon here. Simply because one accesses or amends information in a database does not mean that some type of instantaneous notification is desired. Some information altered in the database may be of simply minor importance – adding a fax number for example. Moreover, the system disclosed here is designed so that patients or their caregivers are notified of a match. Alerting the patient's physician would actually slow down the process in the present system, so a prior art disclosure suggesting that action would in fact teach away from the claims here.

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[9] Claim 3 includes the following language:

> "The method of claim 2, further comprising the step of: (g) accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f)."

Claim 129 includes the following language:

> "A method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:... (e) allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site."

Nor does the asserted motivation suggest the elements added by claims 3 and 129. Claim 3 requires "accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f)." Claim 129 requires "allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site." Even if TVisions does suggest to the art that "alerting physicians within seconds of possible matches of their patients with available or new clinical trials" is desirable, it says nothing of looking to different clinical studies after a match has been made or how subsequent visits to the cite by the participant should be treated.

(3) The Rejection of Claim 15 Under 35 U.S.C. § 103(a)

(a) The Cited Motivation "Speeding Up Patient Recruitment" Does Not Support The Asserted Combination

The Examiner rejected claim 15 over the combination of Baldwin and CenterWatch with Larkin. The Examiner noted that the combination of Baldwin and CenterWatch still lacked the "genetic sequence information" element of claim 15 and argued that Larkin teaches this limitation.[10] The asserted motivation for this combination was that Larkin suggested "speeding up patient recruitment." *Office Action* at 16-17.

How the obviously desirable goal of speeding up patient recruitment would lead one of ordinary skill in the art to include reference to genetic sequence information during the process of determining whether to provide a person notice of a given clinical study is never explained by the Examiner. Indeed, this is typical of the obviousness rejections made in this case. The Examiner has merely recited a broadly desirable goal in the art stated or even implied by a

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[10] Claim 15 includes the following language:

> "The method of claim 2, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database."

particular reference that happens to disclose an element the Examiner needs to meet the claims. That vague goal – suggesting nothing about the specific references at issue or the claim element missing from the Examiner's case - is then used as a justification for combining what would otherwise be seen as separate, unrelated teachings in the art. This is not a proper obviousness rejection because one of ordinary skill in the art, reading the Larkin reference, would not be motivated to combine it with the Baldwin and CenterWatch references simply because of some overarching recognition that faster recruitment is a good thing.

Indeed, here the motivation would go in exactly the opposite direction. Reference to genetic sequence information is not a casual or simplistic activity. Including such information, and all the complexity necessary to reasonably interpret such information, could only slow down the recruitment process.

C. Rejections Based On Alleged Indefiniteness

Two claims stand rejected as indefinite under 35 U.S.C. § 112, second paragraph. The Examiner has rejected claim 14 as indefinite for its reference to "off-line sources." *Office Action* at 3. The claim reads as follows:

> The method of claim 2, wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, ***and other off-line sources***.

(Emphasis added.) The Examiner appears to argue that that the limitation of "other off-line sources" is indefinite because Applicants also listed specific off-line sources in the claim.

Definiteness is based on whether the skilled artisan would understand what is claimed. "The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1994).

On page 37, lines 7-8, of the specification, Applicants state "[t]he notification could alternatively be provided using telephone, mail, fax or any off-line communication means."

Clearly, Applicants intend to broadly capture the concept that this limitation is not limited to on-line sources for the provision of answers from the person cited in the claim. There is nothing improper or hard to understand about that. It is the "off-line" nature of the medium that is important to this particular claim limitation, not the specific species of "off-line" medium. Applicants therefore assert that the claim is easily within the understanding of those of skill in the art.

Claim 15 has also been rejected as indefinite based its recited "genetic sequence information" language. *Office Action* at 3-4. That claim reads as follows:

> The method of claim 2, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database.

The Examiner rejected this claim as indefinite because he believed he could not determine the scope of the claim:

> Is the person or caregiver required to present genetic sequence information when the person or caregiver registers with the database in step a)? If so, then the claim contains a missing step since this information is not included in the claimed registration step. Or is the disease condition of interest that is input by the person or caregiver during the registration process of step a) associated with a particular genetic sequence information? Or are there clinical trials related to specific studies relating genetic sequence information to a specific diseases that relate to the patient's or caregiver's disease condition of interest as submitted during the registration step a)?

Office Action at 3-4.

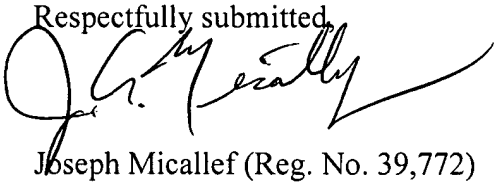
The language of the claim, however, is clear on its face and says nothing of how the genetic sequence information finds its way into the database. Practice of the claimed invention merely requires that the automatically determining step also include "reference to genetic sequence information associated with a person registered in the database." It does not require that the person enter such information during the same visit as the determination step, or during the same visit as the registration step, though both of those scenarios would be covered. Nor does it speak to the specifics of any clinical trial. All that is required by the plain meaning of this

claim language is that reference be made to such information in the context of the determining step. Applicants submit that this claim is clear on its face and readily understood. The indefiniteness rejection should therefore be reversed.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse these Rejections and that the subject application be allowed forthwith.

Respectfully submitted,



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APPENDIX A

PENDING CLAIMS FOR 09/923,385

2. A method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:

(a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database, wherein the registration information includes at least a geographic location of the person, at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies;

(b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information;

(c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person;

(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice;

(e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and

(f) storing answers submitted by the person or caregiver in the database.

3. The method of claim 2, further comprising the step of:

(g) accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f).

4. The method of claim 2, wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study.

5. The method of claim 2, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site.

6. The method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site.

7. The method of claim 2, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver.

8. The method of claim 2, wherein the notice provided in step (d) is sent by regular mail to the person or caregiver.

9. The method of claim 2, wherein the notice provided in step (d) is communicated by telephone to the person or caregiver.

10. The method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of the given clinical study.

11. The method of claim 2, wherein in step (c) a determination is made not to provide the person or caregiver with notice of the given clinical study.

12. The method of claim 2, wherein in step (a) the registration information includes whether the person is interested in clinical study information, whether the person is interested in new medical therapies, or whether the person is interested in participating in clinical studies.

13. The method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of an investigator associated with the study.

14. The method of claim 2, wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources.

15. The method of claim 2, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database.

129. A method for recruiting a person to participate as a subject in a clinical study, comprising the steps of:

(a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database, wherein the registration information includes at least a geographic location of the person, at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies;

(b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information;

(c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the person;

(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice; and,

(e) allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site.

130. The method of claim 2, wherein said questionnaire is a pre-examination questionnaire.

131. The method of claim 130, wherein said pre-examination questionnaire is a screening questionnaire.

132. The method of claim 130, wherein said pre-examination questionnaire is a pre-screening questionnaire.

133. The method of claim 2, wherein said questionnaire is a pre-screening questionnaire.

134. The method of claim 2, wherein said questionnaire is a screening questionnaire.

135. The method of claim 134, wherein said screening questionnaire is protocol specific.

136. The method of claim 2, wherein said questionnaire is designed for screening for clinically appropriate persons.

137. The method of claim 2, wherein said questionnaire requests information regarding inclusion/exclusion criteria.

138. A method for recruiting an individual to participate as a subject in a clinical study, comprising the steps of:

(a) presenting at least one web page to permit an individual to be registered with a database by indicating whether the individual wishes to receive notice of one or more clinical studies and registration information, wherein the registration information includes at least a geographic location, a disease condition of interest to the individual, and contact information;

(b) automatically registering the individual with the database upon receipt of the registration and indicating information;

(c) after step (b), automatically determining, in accordance with the indicating information and the registration information, whether to provide the individual or caregiver with notice of a clinical study associated with said disease condition;

(d) providing the individual notice of said clinical study;

(e) presenting a screening questionnaire associated with said clinical study; and

(f) storing answers submitted by the individual in the database.

139. A method comprising the steps of:

(a) presenting at least one web page to permit an individual to be registered with a database by submitting information indicating whether notice of one or more clinical studies is desired and registration information, wherein the registration information includes at least a geographic location, a disease condition of interest, and contact information;

(b) automatically registering the individual with the database upon receipt of the registration and indicating information;

(c) automatically determining, in accordance with the indicating information and the registration information, whether to provide notice of a clinical study related to said disease condition;

(d) providing notice of said clinical study;

(e) presenting a screening questionnaire associated with said clinical study; and

(f) storing in the database answers submitted in response to said questionnaire.

140. A method of administering a database comprising the steps of:

(a) storing in a computer memory information indicating whether notice of one or more clinical studies associated with a particular disease condition is desired and registration

information that indicates at least a geographic location, said disease condition of interest, and contact information; and,

(b) storing in said memory responses to a questionnaire associated with said notice.

141. The method of claim 140, wherein said questionnaire is a pre-examination questionnaire.

142. The method of claim 141, wherein said pre-examination questionnaire is a screening questionnaire.

143. The method of claim 141, wherein said pre-examination questionnaire is a pre-screening questionnaire.

144. The method of claim 140, wherein said questionnaire is a pre-screening questionnaire.

145. The method of claim 140, wherein said questionnaire is a screening questionnaire.

146. The method of claim 145, wherein said screening questionnaire is protocol specific.

147. The method of claim 140, wherein said questionnaire is designed for screening for clinically appropriate persons.

148. The method of claim 140, wherein said questionnaire requests information regarding inclusion/exclusion criteria.

149. A computer readable medium comprising computer executable instructions for performing the steps of:

(a) storing in a computer memory information indicating whether notice of one or more clinical studies is desired and registration information that includes at least a geographic location, a disease condition of interest, and contact information; and,

(b) storing in said memory responses to a screening questionnaire associated with said notice.

150. A computer readable medium comprising computer executable instructions for performing the steps of:

(a) providing information relating to at least one web page to permit an individual to be registered with a database by submitting information indicating whether notice of a clinical study is desired and a disease condition of interest;

(b) registering the individual with the database upon receipt of said information;

(c) determining in accordance with said information whether to provide notice of a clinical study related to said disease condition;

(d) providing notice of said clinical study;

(e) presenting a screening questionnaire associated with said clinical study; and,

(f) storing in the database answers submitted in response to said questionnaire.

151. A computer readable medium comprising computer executable instructions for performing the steps of:

(a) providing a web interface for registering an individual with a database by submitting information indicating whether notice of one or more clinical studies is desired and registration information, wherein the registration information includes at least a geographic location, a disease condition of interest, and contact information;

(b) determining whether to provide notice of a clinical study related to said disease condition;

(c) providing a web interface for submitting answers to a screening questionnaire associated with said clinical study; and,

(e) storing said answers in the database.